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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,699	12/04/2003	Steven M. Ruben	PS737	8782

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,699	RUBEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-23 are pending in the application.

Election/Restrictions

[3] Restriction to *one* of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15, and 21, drawn to an isolated nucleic acid, a recombinant vector, a method of making recombinant host cell, a recombinant host cell, a method of making an isolated polypeptide, and a gene, classified in class 435, subclass 69.1.

II. Claims 11-12 and 16, drawn to an isolated polypeptide, classified in class 530, subclass 350.

III. Claims 13, drawn to an isolated antibody, classified in class 530, subclass 387.9.

IV. Claim 23, drawn to a polypeptide binding partner, classified in class 530, subclass 350.

V. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition by administering a polypeptide, classified in class 514, subclass 2.

VI. Claim 18, drawn to a method of diagnosing a pathological condition by determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6.

VII. Claim 19, drawn to a method of diagnosing a pathological condition by determining the presence or amount of expression of a polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 20, drawn to a method for identifying a polypeptide binding partner, classified in class 435, subclass 7.1.

IX. Claim 22, drawn to a method for identifying an activity in a biological assay, classified in class 435, subclass 7.1.

[5] If applicant should elect the invention of Group I or VI, restriction to a single nucleic acid encoding SEQ ID NO:65-118 is also required under 35 U.S.C. 121. Thus, if applicant elects Group I or VI, applicant is further required under 35 U.S.C. 121 to elect a single nucleic acid encoding SEQ ID NO:65-118 for examination on the merits.

[6] If applicant should elect the invention of Group II, III, IV, V, VII, VIII, or IX, restriction to a single polypeptide of SEQ ID NO:65-118 is also required under 35 U.S.C. 121. Thus, if applicant elects Group II, III, IV, V, VII, VIII, or IX, applicant is further required under 35 U.S.C. 121 to elect a single polypeptide of SEQ ID NO:65-118 for examination on the merits.

[7] The inventions are distinct, each from the other because:

[8] The polynucleotides encoding SEQ ID NO:65-118 are structurally distinct, encode structurally distinct polypeptides, and no single polynucleotide encoding SEQ ID NO:65-118 would render any of the others obvious to one of ordinary skill in the art.

[9] The polypeptides of SEQ ID NO:65-118 are structurally distinct and because of their structural distinctness, elicit different antibodies and have distinct binding partners, and no single polypeptide of SEQ ID NO:65-118 would render any of the others obvious to one of ordinary skill in the art.

[10] The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of group II, see, *e.g.,* the nucleic acid of claim 1, part (i), which is a complementary nucleic acid and therefore would not encode the polypeptide of group II. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. For example, a nucleic acid which hybridizes to SEQ ID NO:11, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift

mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO:65. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Also, the polypeptide can be made using purely synthetic means. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of

technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 13 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group II, the antibody of group III, and the binding partner of group IV are patentably distinct for the following reasons: While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. The invention of group IV is not required to be an antibody and encompasses small molecule binding compounds that have no structural relationship to the antibody of group III. Thus the polypeptide of group II, the antibody of group III, and the binding partner of group IV are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III or a binding partner of group IV is dependent upon the correlation between the scope of the polypeptides that the antibody or binding partner binds and the scope of the antibodies or binding partners that would be generated using the polypeptide. In this case, the polypeptide of group II is a large molecule which contains

potentially hundreds of regions to which an antibody or binding partner may bind, whereas the antibody of group III or the binding partner of group IV is defined in terms of its binding specificity to a small structure within, *e.g.,* SEQ ID NO: 65. Thus the polypeptide of group II would result in the production of antibodies or binding partners outside the scope of group III or IV. Furthermore, an antibody of group III or a binding partner of group IV would not specifically bind all of the polypeptides of group II because the polypeptides of group II encompass mutants and variants. Therefore the polypeptide, antibody, and binding partner are patentably distinct. Furthermore, searching the inventions of groups II, III, and IV together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide, an antibody, and an undefined binding partner, each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibody of group III or the binding partner of group IV. Furthermore, antibodies which bind to an epitope of a polypeptide of group II or binding partners that bind to the polypeptide of group II may be known even if a polypeptide of group II is novel. Similarly, an amino acid sequence search for fragments of the polypeptide is required to determine the novelty and nonobvious of the antibodies of group III, however such a search is not required or sufficient to identify all of the polypeptides of group II. In addition, the technical literature search for the polypeptide of group II and the antibody of group III or the binding partner of group IV are not coextensive, e.g.,

antibodies or binding partners may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I, the antibody of group III, and the binding partner of group IV are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Binding partners, which encompasses small molecule organic compounds and other polypeptides, are structurally distinct molecules. In the present claims, a polynucleotide of group I will not encode an antibody of group III or a binding partner of group IV, and the antibody of group III or the binding partner of group IV cannot be encoded by a polynucleotide of group I. Therefore the antibody, the binding partner, and polynucleotide are patentably distinct. The antibody, the binding partner, and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of groups I, III, and IV together would impose a serious search burden since a search of the

polynucleotide of group I would not be used to determine the patentability of an antibody of group III or the binding partner of group IV, and vice-versa.

[11] The polynucleotide of Group I is unrelated to the method(s) of Groups V and VII-IX as it is neither used nor made by the method(s) of Groups V and VII-IX.

[12] The polynucleotide of Group I and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I can be used for protein expression.

[13] The polypeptide of Group II is unrelated to the method of Group VI as it is neither used nor made by the method of Group VI.

[14] The polypeptide of Group II and the methods of Groups V and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used as an antigen in the production of antibodies.

[15] The antibody of Group III is unrelated to the method(s) of Groups V-IX as it is neither used nor made by the method(s) of Groups V-IX.

[16] The polypeptide binding partner of Group IV is unrelated to the method(s) of Groups V-IX as it is neither used nor made by the method(s) of Groups V-IX.

[17] Inventions VI and (V and VII-IX) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of group VI and the methods of groups V and VII-IX are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for practicing the claimed methods differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions VI and (V and VII-IX) are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups VI and (V and VII-IX) have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups VI and (V and VII-IX) together.

[18] The methods of groups V and VII-IX are directed to the use of related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or

effect. See MPEP § 806.05(j). In the instant case, each of the methods of groups V and VII-IX comprise different method steps and achieve different results.

[19] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-IX are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or sequence search for each Group and thus, co-examination of the inventions of Groups I-IX would be a serious burden on the examiner.

[20] It is noted that claims 1-23 will be examined only to the extent the claims read on the elected subject matter.

[21] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[22] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[23] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and

Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656